



c-LEcta
for tomorrow's industry

DENARASE®

The GMP nuclease for viral vector manufacturing

During the manufacturing of viral vectors for cell- and gene therapies, residual DNA and RNA from host cells and plasmids must be removed. Endonucleases originating from *Serratia marcescens* are commonly added to degrade DNA and RNA, followed by purification. c-LEcta's DENARASE® – an endonuclease from *Serratia marcescens* – fulfills the highest quality standards in order to progress quickly from pre-/clinical towards commercial manufacturing of viral vectors.

DENARASE® endonuclease fulfills the highest standards:

High Safety and Quality

- Manufacturing free of animal derived raw materials and antibiotics
- Endotoxin-free expression host: Patent-protected production process based on *Bacillus sp.*
- High activity and high purity of $\geq 99\%$

Full Compliance

- Produced under EU GMP conditions in Germany
- Certified compliance with the EXCiPACT and ANSI NSF 363 Standard (meeting GMP/GDP for pharmaceutical excipients)
- Dedicated regulatory support for US-market approvals of pharmaceutical products via own US FDA Drug Master File



DENARASE® endonuclease is already established in the biopharma industry:

6 of 10 big pharma players qualified DENARASE®

DENARASE® is applied in:

- **4 Commercial**
 - **40+ Clinical Phase I-III**
- viral vector manufacturing processes**

Technical support

Our DENARASE® validation report is available on demand, containing detailed information:

- Product and manufacturing description
- Detailed product release specifications
- Application data for common operating conditions
- Regulatory certificates
- Transport and storage stabilities

Please ask our experts for further details.

Available DENARASE® products:

Art. No.	Size	Purity	Activity
20804-100k	100 kU	≥ 99 %	> 250 U/μl
20804-500k	500 kU	≥ 99 %	> 250 U/μl

Produced under EU GMP and filled under ISO 9001 for research and development applications

Art. No.	Size	Purity	Activity
20804-1M	1 MU	≥ 99 %	> 250 U/μl
20804-5M	5 MU	≥ 99 %	> 250 U/μl

Produced and filled under GMP, suitable for GMP Biomanufacturing

About us

c-LEcta is a world-leading biotechnology company with a focus on enzyme engineering and applications in regulated markets like the food and pharmaceutical industries. The company is based in Leipzig, Germany, and has established itself as a leading player in the realization of high-value biotech products, in the form of in-house developments or in close cooperation with industry. The company currently employs more than 100 people.

c-LEcta.com

Contact us for further information.

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